



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,944	08/28/2003	Itzhak Bentwich	050992.0300.CPUS08	1943
37808	7590	07/13/2006	EXAMINER	
ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			DEJONG, ERIC S	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 07/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/604,944	Applicant(s) BENTWICH, ITZHAK	
	Examiner Eric S. DeJong	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 11, 12, 14 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Election/Restrictions

The withdrawal of claims drawn to isolated RNA encoded by the nucleic acid of claim 1 (further drawn to the elected sequence of SEQ ID NO: 14) has been reconsidered and claims 2, 5, 6, 7, 21, 22, 24 and 25 are rejoined. Currently, claims 1, 2, 5-8, 11, 12, 14, and 21-26 are under examination.

Oath/Declaration

Applicants declaration that the names "Issac" and "Itzak" used interchangeable on a number of related pending patent applications both refer to the same inventor is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-8, 11, 12, 14, and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 now recites the limitation "wherein the nucleic acid comprises about 50 to about 120 nucleotides", in line 2 of said claim. However claim 1 also recites "an isolated nucleic acid comprising the sequence of SEQ ID NO: 14", wherein SEQ ID NO:

14 is a 77 nucleotide sequence. It is unclear how any nucleic acid comprises about 50 to about 76 nucleotides" while still meeting the limitation of "comprising the sequence of SEQ ID NO: 14". Claims 2, 5-8, 11, 12, 14, and 21-25 are also included under this rejection due to their dependence from claim 1.

Claim 26 recites the limitation "the sequence set in SEQ ID No: 14" in lines 1 and 2 of said claim. It is unclear from this claim what of the term "sequence set" is intended to encompass. The term "sequence set" does not indicate any particular ordering of nucleic acids selected from SEQ ID NO: 14, nor does said term refer to the frequency a particular amino acid from SEQ ID NO: 14 may be selected. Alternatively, the term "sequence set" may refer to a selection of contiguous nucleic acids present in SEQ ID NO:14. As such, the metes and bounds of the instant claim is rendered indefinite.

For the purpose of continuing examination, the term "sequence set" has been construed to read as any selection of nucleic acids from SEQ ID NO: 14.

Double Patenting

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 1, 8, 11, 12, 14, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, and 14 of copending Application No. 10/536,560; claims 1-8, 12, and 14 of copending Application No. 10/605,838; claims 1-8, 12, and 15 of copending Application No. 10/605,840; claims 1-8, 12, and 14 of copending Application No. 10/707,003; claims 1, 2, and 4 of copending Application No. 10/708,952; and claims 1, 2, and 5 of

copending Application No. 10/709,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identified claims in the above copending applications are generically drawn to a plurality sequences that are provided for in their respective disclosure. Since the above identified copending applications are related as child applications of the instant application (parent), the nucleotide sequences disclosed therein encompass SEQ ID No. 14 as is claimed in the instant application. Therefore the instant claims, which are specific to SEQ ID No. 14, are encompassed by the more broadly drawn claims of the above identified copending applications encompass a plurality of disclosed sequences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11, 12, 14, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Brander et al.

The claims are drawn to an isolated nucleic acid comprising the sequence of SEQ ID No. 14, a vector comprising SEQ ID No. 14, a means for inserting said vector into a cell, a probe comprising SEQ ID No. 14, a gene expression diction system

comprising the probe comprising SEQ ID No. 14, and an isolated nucleic acid complementary to the nucleic acid comprising SEQ ID No. 14.

[Claims 1 and 23]: Brander et al. disclose the isolation of the and HIV-1 viral sequence for the Gag p17 region (gag) gene, and the subsequent submission to Genbank under accession number AF017925, which has 100% identity to that of the elected sequence, SEQ ID No. 14 (see Brander et al., page 2560, col. 2., lines 38-46) and a nucleic acid complementary to a nucleic acid comprising SEQ ID No. 14.

[Claims 8, 11, and 12]: Brander et al. further discloses that the identified gag genes were isolated using routine molecular cloning techniques relying on PCR and cell transformations involving vector constructs containing the disclosed sequences (see Brander et al. pg 2560, col. 1, line 5 through col. 2, line 37), which reads on the instantly claimed limitations drawn to a vector, and a probe comprising SEQ ID No. 14, as well as a means for inserting said vector into a cell.

[Claim 14]: Brander et al. further sets forth that the identified HIV-1 gag sequences were relied upon in a quantitative analysis of the expression of HIV-1 gag protein and variants thereof in HIV-1 cell lines (see page 2560, col. 2, line 48 through page 2564, col. 1, line 25), which reads upon the instantly claimed gene expression detection system comprising a probe comprising SEQ ID No. 14 and a gene expression detector.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 5, 6, 7, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by McSwiggen (Pub. No. US 2003/0175950).

The claims are drawn to an isolated RNA according to 18 to 24 nucleotides encoded by the nucleic acid of claim 1, which comprises SEQ ID NO:14.

McSwiggen sets forth methods and reagents useful for modulating HIV gene expression, specifically relating to small interfering RNA (siRNA). McSwiggen further discloses SEQ ID NOs: 502, 522, 527, 543, 569, 578, 586, 587, 602, 620, 623, 662, 680, 701, 1240, 1260, 1265, 1281, 1307, 1316, 1324, 1325, 1340, 1358, 1361, 1400, 1418, and 1439, which are each 19 nucleotides in length and have 100% identity to a 19mer sequence present in SEQ ID NO: 14 as instantly claimed (see Table I of McSwiggen and claims 3, 8, and 9).

Response to Arguments

Applicant's arguments filed 04/10/2006 have been fully considered but they are not persuasive.

Applicant's indication of SEQ ID NOs: 294, 781, 782, and 14496 from copending application No. 10/536,560 as being identical to the elected sequence of SEQ ID NO: 14 under examination in the instant application is acknowledged. Since said copending

application contains generic claims open and reading on SEQ ID NOs: 294, 781, 782, and 14496 disclosed therein, the provisional Double Patenting rejection has been amended to also include application No. 10/536,560.

In regards to claims provisionally rejected for obviousness-type double patenting, applicants request that the provisional rejection be withdrawn that since the provisional rejection is the only outstanding rejection.

In response, it is noted that all claims in the instant application remain rejected on grounds other than obviousness-type double patenting. As such the provisional rejection of claims for obviousness-type double patenting will be maintained.

In regards to the rejection of claims under 35 USC § 102(b), applicants argue that the sequence disclosed by Brander et al. is 451 nucleotides in length, and that the instant claim 1 recites that the nucleic acid is from about 50 to 120 nucleotides. As such, the instantly claimed sequence is distinct from that disclosed by Brander et al.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the nucleic acid is from about 50 to 120 nucleotides) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, claim 1 recites the limitation of "the nucleic acid comprises about 50 up to about 120 nucleotides" in line 2 of said claim. The recitation of "the nucleic acid comprising" is open language and as such any sequence

of about 50 nucleotide or longer in length would meet the instant limitation. As such, the 451 nucleotide sequence disclosed by Brander et al. satisfies the limitation of comprising from about 50 to 120 nucleotides as recited in claim 1.

Conclusion

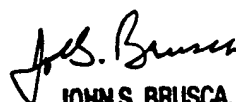
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ



 7 July 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER